

## **REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Non-Final Office Action dated August 20, 2008 are respectfully requested in view of the arguments and amendments presented herein.

This amendment is timely filed.

### **Status of the Claims**

In the present response, claims 1-25 are cancelled, claim 26 is amended, and claims 27-51 are added. Therefore, claims 26-51 are pending in the application with claims 26, 33, and 45 being independent.

### **Explanation and Support of Amendment**

Applicants submit that each of the foregoing amendments is fully supported by the specification. For the convenience of the Office, specific examples of support are noted below:

Regarding new claims 27, 34, and 46, support for reciting that the constriction has a diameter less than 0.51 mm (0.020 in), is found in the present application, e.g., in originally filed claim 18.

Regarding new claims 28, 35, and 47, support for reciting that the constriction has a diameter less than 0.1 mm (0.005 in), is found in the present application, e.g., in originally filed claim 19.

Regarding new claims 29, 36, and 48, support for reciting a third channel for a gas flow, is found in the present application, e.g., in originally filed claim 20.

Regarding new claims 30 and 37, support for reciting that the first channel is annular, is found in the present application, e.g., at page 7, line 6.

Regarding new claims 31, 38, and 49, support for reciting that the drying chamber has a gas inlet stream having an inlet temperature of at least 90°C, is found in the present application, e.g., at page 9, line 29.

Regarding new claims 32, 39, and 50, support for reciting that the drying chamber has a gas outlet stream having an outlet temperature of at least 50°C, is found in the present application, e.g., at page 9, line 21.

Regarding new claim 40, support for reciting that the pharmaceutical liquid comprises an active agent and an excipient, is found in the present application, e.g., at page 13, lines 23-25.

Regarding new claims 41 and 51, support for reciting that the particles have a rugosity above 2, is found in the present application, e.g., at page 9, line 24.

Regarding new claim 42, support for reciting that the particles have a density below 0.5 g/cm<sup>3</sup>, is found in the present application, e.g., at page 10, line 2.

Regarding new claim 43, support for reciting that the particles have a glass transition temperature above 35°C, is found in the present application, e.g., at page 14, line 12.

Regarding new claim 44, support for reciting that the particles have a mass median diameter less than 20 µm, is found in the present application, e.g., at page 16, line 6.

Regarding new claim 45, support for reciting a first annular channel for a liquid flow and a second annular channel for an atomizing gas flow, is found in the present application, e.g., at page 6, lines 6-12.

Accordingly, no new matter has been added by the amendments.

### **Response to Restriction Requirement**

Claims 1-16 have been withdrawn from consideration as being directed to non-elected subject matter. In response, claims 1-16 have been cancelled.

### **Claim and Specification Objections**

The specification and claims 18, 19, 23, and 24 are objected for the use of English units. In response, the specification and claims now also include metric units.

### **Response to § 112 Rejection**

Claims 17-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons set forth at page 3 of the Office Action. Although Applicants disagree with the rejection, in order to advance prosecution, claims 17-25 have been cancelled, and claim 26 has been amended to even more clearly recite the present invention and to eliminate the language objected to by the Examiner. In this regard, any amendments to the claims which have not been specifically noted as being made to overcome a rejection based upon the prior art, should be considered to have been intended to clarify the claims and not narrow the claims, such that no estoppel should be deemed to attach thereto.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

### **Response to § 102 Rejection**

Claims 17, 20-22, and 25 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,352,209 to Skeath et al. In response, claims 17, 20-22, and 25 have been cancelled without prejudice or disclaimer.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

### **Response to § 103 Rejection**

#### ***Skeath***

The Office Action rejects claims 18, 19, 23, and 24 under 35 U.S.C. § 103(a) as being unpatentable over Skeath. In response, claims 18, 19, 23, and 24 have been cancelled without prejudice or disclaimer.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

#### ***Gordon in view of Skeath***

The Office Action rejects claim 26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,077,543 to Gordon et al. in view of Skeath. The

Office asserts, "Gordon et al. discloses a process of preparing dispersible dry powders that includes an atomizing operation (10) that produces droplets of a liquid medium which are then dried in a drying operation (20) and then collected in a separation operation (30)". Office Action at pages 5-6. The Office concedes, "Gordon et al. does not however disclose the specific details of the atomizer that are recited in claim 26." Office Action at 6.

The Office, however, asserts that Skeath et al. shows an atomizer for forming droplets, the atomizer comprising: a first channel (64) through which a liquid may flow, the channel comprising a constriction (where the diameter gets smaller toward the end just before it reaches the main gas channel) for spreading the liquid into a thin film (column 5, lines 49-55) in the channel; and a second channel (the main gas channel in the center of the atomizer) through which an atomizing gas may flow, the second channel being positioned so that the atomizing gas impinges the liquid thin film in a manner which produces droplets having a diameter less than 35 micrometers (column 2, lines 5-10).

The Office then argues that it would have been obvious "to use the atomizer of Skeath et al. in the atomization operation of Gordon et al., instead of the atomizer of Gordon et al., in order to atomize the liquid into droplets having a diameter less than 10 micrometers, as taught by Skeath et al. (column 2, lines 5-10)." Office Action at page 6.

In response, Applicants respectfully submit that the Examiner has failed to provide an adequate reason for combining the teachings of Gordon and Skeath. For instance, Gordon involves dry powder compositions and methods for their preparation. In contrast, Skeath involves atomizing devices and does not disclose making powders.

Further, the Office and the cited documents fail to provide any reason for using the relatively more complicated system of Skeath to provide droplets having a diameter less than 10 micrometers when making dry powders. To the contrary, since the system of Skeath is relatively more complicated, a skilled artisan would have recognized that its nozzle is more difficult to use and more expensive. Thus, a skilled artisan would have avoided using the relatively more complicated system of Skeath without a particular reason to incur additional burden and cost.

In view of the above, Applicants respectfully request withdrawal of this ground of rejection.

### **New Claims**

For the sake of completeness, Applicants note that new claims 27-51 have been added. Applicants respectfully submit that the cited documents fail to disclose or render obvious new claims 27-51.

### **CONCLUSION**


In view of the foregoing, the Applicant(s) submit that all outstanding issues in this case have been resolved, and that all pending claims in their current form are allowable. A Notice of Allowance is therefore respectfully requested. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3244.

Respectfully submitted,

Nektar Therapeutics

Date: 20 Nov 08

  
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## **Appendix**

The impingement of the atomization gas annulus onto the this annular film of liquid in the version of FIG. 2 provides improved droplet formation. The droplets are formed by using the atomization gas annulus to pull droplets off the edge of the expanding conical surface at the forward end **70** of the first annular channel **60**. By both thinning the liquid and increasing the amount of surface area per unit volume of liquid for interaction with the atomization gas, the efficiency of atomization is improved. This allows for smaller droplet sizes to be created using less atomization gas. The thickness of the thin film allows for the formation of desired droplets. In one version, the thin film is less than 0.51 mm (0.020 in), more preferably less than 0.1 mm (0.005 in), more preferably less than 0.05 mm (0.002 in), and most preferably about 0.03 mm (0.001 in). It has also been determined that by forming the thin film by nature of the shape of the channel and then impinging the thin film with a gas, the size distribution of the droplets formed is within a narrower range and is more controllable.